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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,842	05/02/2007	Jo Klaveness	PN0396	7406
36335 7590 05/29/2011 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231				
EXAMINER SAMALA, JAGADISHWAR RAO				
ART UNIT 1618		PAPER NUMBER		
NOTIFICATION DATE 05/20/2011		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

MDUSPatents@ge.com  
Lori.allaire@ge.com

### Office Action Summary

**Application No.**

10/582,842

**Applicant(s)**

KLAVENESS ET AL.

**Examiner**

JAGADISHWAR SAMALA

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 6 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Amendment and Remarks filed on 02/22/2011.

- Claims 1, 6 and 8 have been amended.
- Claims 3-5, 7 and 9-13 have been cancelled.
- Claims 1, 2, 6 and 8 are pending and presented for examination.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 6 is drawn to a contrast agent is of formula I, V-L-R (I) wherein V is an organic drug-like small molecule having affinity for the urokinase receptor... The recitation that V is an organic drug-like small molecule is ambiguous because it is unclear to what extent a small molecule should be "like" a drug to be considered sufficiently drug-like to be within the scope of the claims. The term drug-like is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder et al (US 2003/0044353) **are withdrawn** in light amendment to claims.

Claims 1-2, 6 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Lauffer et al (US 2002/0034476) **are withdrawn** in light amendment to claims.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness et al (US 6,264,914) in view of Lauffer et al (US 2002/0034476) **are withdrawn** in light amendment to claims.

However, upon further consideration a new ground(s) of rejection is prepared as follow.

Claims 1-2, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt et al (US 2007/0066798) in view of Achilefu et al (2005/0271592).

Claims are drawn to an agent of formula V-R-L wherein: V is one or more vector moieties that target COX-2, urokinase receptor, epidermal growth factor receptor or vascular endothelial growth factor; L is a bond and R is a reporter moiety comprising a cyanine dye.

Schmitt discloses a reagent kit comprising diagnostic and therapeutic application of amino acid sequence-specific antibodies against the urokinase receptor having high affinity for tumor cell-expressed receptors (abstract). The urokinase receptor (uPAR) is a particularly preferred tumor-specific determinant. The method for detecting cells in a biological sample comprises contacting the sample with at least two different binding molecules which recognize the cells to be detected (0009 and 0020). The binding molecules are preferably antibodies or antibody fragments and in particular monoclonal antibodies (0016). The fluorescent dyes such as fluoresce in and derivatives, phycoerythrin, rhodamine... can be directly e.g., covalently conjugated with the primary binding molecule that are specific for the cells to be detected, or the fluorescent dye can

be conjugated to secondary binding molecules which are in turn directed against the primary binding molecules (0023). Additional disclosure includes that due to high affinity for tumor uPAR these antibodies or fragments thereof are also suitable as diagnostic agents for detecting tumor cells in a biological sample and in particular for detecting disseminated tumor cells in bone marrow (0035).

Schmitt fails to incorporate cyanine dye in the composition.

Achilefu teaches compositions of cyanine and indocyanine dye biconjugates with bioactive molecules for diagnosis and therapy, and particularly for visualization and detection of tumors. The cyanine dyes can be conjugated to bioactive peptides, carbohydrates, drugs, or other bioactive agents (abstract). Additional disclosure includes that the bioconjugates may be utilized, for example, to enhance tumor detection, preserve the fluorescence efficiency of the dye molecules, do not aggregate in solution, form starburst dendrimers, are capable of absorbing and/or emitting light in the near infrared region and can be rendered tissue specific (0009).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cyanine dyes into Schmitt's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Achilefu teaches that cyanine dyes with intense absorption and emission in the near-infrared region are particularly useful because biological tissues are optically transparent in this region (0004). And also incorporation of cyanine dyes into compositions form starburst dendrimers which prevent aggregation in solution and have multiple attachment sites proximal to the dye chromophore for ease of forming bioactive

molecules. The presence of rigid and extended chromophore backbone enhances their fluorescence quantum yield and extends their maximum absorption beyond 800 nm (0041). Therefore, one ordinary skill in the art would have had a reasonable expectation of success because Achilefu teaches that dye-conjugates are useful for various biomedical applications such as tomographic imaging of organs, monitoring of organ functions, coronary angiography, fluorescence endoscopy, detection, imaging and therapy of tumors laser guided surgery, photoacoustic methods and sonofluorescent methods.

### **Double Patenting**

Claims 1,2, 6 and 8 provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims of co-pending Appl. Ser. Nos. 10/573,604 and 10/582,680 **are withdrawn** in view of Abandonment of the copending applications.

However, Applicant's request to hold the double patenting rejection over claims of copending applications serial Nos. 10/573,606 and 10/582,893 in abeyance is acknowledged and maintained.

### **Conclusion**

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./  
Examiner, Art Unit 1618

/Jake M. Vu/  
Primary Examiner, Art Unit 1618